

REMARKS/ARGUMENTS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

The title of the invention as shown on the Filing Receipt, on the application as published and in PAIR, is missing the minus sign after "CD25." Accordingly, Applicants have amended the title to correct this omission. Clearly, no new matter is added by this amendment, as it finds support throughout the original specification, for example, in the very first line of the description.

As a result of the amendments above, claims 9, 11 and 29-34 are pending. Claim 9 has been amended to correct a typographical error, as noted in the Office Action (Office Action dated 20 April 2006, page 3, #3), and has further been amended to clarify that the method comprises a step of separating CD4⁺ CD25⁺ cells from CD4⁺ CD25⁻ cells. Support for these amendments can be found in the specification, for example: on page 3, paragraph 3 (part labeled "(2)"); on page 9, paragraph 2, lines 7-8, and in working Example 1 on page 14; see also Figure 1 as well as its figure legend on page 5. Claim 10 has been canceled. Claim 30 has been amended as further discussed below. Support for claim 30 as amended above can be found in Figure 3 and the Figure 3 legend on page 6, paragraph 4 (note: the Figure legend uses the term "suppress"), and also on page 9, second paragraph, lines 2-4. Finally, new claims 31-34 have been added. Support for new claim 31 can be found, for example: on page 3, first full paragraph; in working Example 4, pages 15-17; and in Figures 3 and 4. New claim 32 finds support in the specification, for example, on page 9, second paragraph, lines 7-12; also on page 3, paragraph 3 (part labeled "(2)"); and in the data shown in Figure 1 and described in the Figure 1 legend on page 5, paragraph 4. New claim 33 finds support in the specification, for example, on page 9,

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first paragraph, last six lines; in the data shown in Figure 3 and described in the Figure 3 legend on page 6, paragraph 4; and in Figure 4 and the Figure 4 legend on page 7, paragraph 2, part "(A)." New claim 34 finds support in the specification, for example in the data shown in Figure 3 and the Figure 3 legend on page 6, paragraph 4; and on page 9, second paragraph, lines 2-4.

No new matter has been added by way of amendment. Reexamination and reconsideration of the claims is respectfully requested.

The Claims Meet the Requirements of 35 U.S.C. § 112, First Paragraph.

In keeping with the spirit of the Examiner's suggestion in the Office Action (page 2, #4), claim 30 has been amended to recite that the Tr1-like regulatory cells suppress the proliferation of syngeneic CD4⁺ T cells. As noted above, support for the amendment can be found in Figure 3 and the Figure 3 legend on page 6, paragraph 4 (note: the Figure legend uses the term "suppress"), and also on page 9, second paragraph, lines 2-4. In view of this amendment, Applicants respectfully request that this rejection of claim 30 be withdrawn.

The Office Action (page 2, #5) has rejected claims 9-11 and 29-30 as failing to meet the possession test. Applicants note that claim 9 (and therefore claims 11, 29, and 30, which depend from or incorporate the limitations of claim 9) has been amended in accordance with the indication in the Office Action (page 3, first full paragraph) that:

Applicant is in possession of a method for producing Tr1-like regulatory cells, comprising anergizing CD4⁺ CD25⁻ T cells by contacting the CD4⁺ CD25⁻ T cells with CD4⁺ CD25⁺ T cells *ex vivo* or *in vivo*.

In view of this amendment, Applicants respectfully request that this rejection of the claims be withdrawn.

The Office Action (page 3, #6) has rejected claims 9-11 and 29-30 for lack of enablement. Applicants note that claim 9 (and therefore claims 11, 29, and 30, which depend from or incorporate the limitations of claim 9) has been amended in accordance with the indication in the Office Action (page 4, first full paragraph) that the specification is enabling for:

A method for producing Tr1-like regulatory cells, comprising anergizing CD4⁺ CD25⁻ T cells by contacting the CD4⁺ CD25⁻ T cells with CD4⁺ CD25⁺ T cells *ex vivo* or *in vivo*.

In view of this amendment, Applicants respectfully request that this rejection of the claims be withdrawn.

The Claims Meet the Requirements of 35 U.S.C. § 102(a)

The Office Action has rejected claims 9-11 and 29-30 under 35 U.S.C. § 102(a) as being anticipated by Dieckmann *et al.* (2002), *J. Exp. Med.* 196: 247-253. Applicants point out that the Dieckmann article lists the present inventors in addition to Cord Henrik Bruett, Heidi Ploettner and Manfred Bernhard Lutz. According to MPEP § 2132.01, this rejection can be "overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work." Attached is the declaration of the Applicants, Dr. Gerold Schuler and Dr. Detlef Dieckmann, establishing the Dieckmann article is describing their own work.

In view of this declaration, Applicants respectfully request that this rejection of the claims be withdrawn.

The Claims Meet the Requirements of 35 U.S.C. § 102(b)

The Office Action has rejected claims 9-11 and 29-30 under 35 U.S.C. § 102(b) as anticipated by Thornton *et al.* (1998) *J. Exp. Med.* 188: 287-296. Claim 10 has been canceled. Claim 9 (and therefore also claims 10, 29, and 30, which are dependent on or incorporate the limitations of claim 9) has been amended to require that the claimed cells are *human*. The Thornton reference only discloses work performed in *mice*. In view of the amendment to the claims, the Thornton reference does not anticipate the claimed invention. Accordingly, Applicants respectfully request that this rejection of the claims be withdrawn. Moreover, Applicants note that, as described in the present specification (see, *e.g.*, Summary of the Invention beginning on page 2, last paragraph), although CD4⁺ CD25⁺ cells had been previously studied in rodents, it was not known whether a similar cell population played a similar role in humans.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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